The amendments to Claims 31, 34, 41, 42, 49, 50 and 94 are supported by the specification at page 17, lines 15-18; page 19, lines 7-8; and the drawings as originally filed.

The amendments to Claims 38 and 46 are supported by the specification at page 13, lines 4-5; page 14, line 21; and the drawings as originally filed.

The amendments to Claim 53 are supported by the drawings as originally filed.

Response to 35 U.S.C. § 102 (e) Rejection

Applicant's attorney thanks the Examiner for a brief interview on October 16, 2002 to better understand the rejection based on pre-AIPA 35 U.S.C. § 102(e). As explained below, Applicant remains convinced that the rejection under pre-AIPA 35 U.S.C. § 102(e) is erroneous.

Claims 29, 31-34, 36-38, 40-42, 44-46, 48-49, 52, 54-71, 73, 75, 77-81, 83, 85-88, 90-93 and 96 were rejected under pre-AIPA 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,385,551 to Shaw ("Shaw"). Applicant respectfully submits that the Examiner cannot rely on Shaw to reject the above mentioned claims under pre-AIPA 35 U.S.C. § 102(e).

Pre-AIPA 35 U.S.C. § 102(e) requires that "the invention was described in a patent granted on an application for patent by another...."[1] In other words, for a proper rejection under pre-AIPA 35 U.S.C. § 102(e), "[t]he inventive entity of the application must be different than that of the reference." MPEP § 706.02(a). The inventive entity of the instant application is not different from that of the Shaw reference. Thomas J. Shaw is the sole inventor of both the instant application and the Shaw reference. *See* "Declaration of Thomas J. Shaw Under 37 C.F.R. § 1.132" as attached hereto. Accordingly, the rejection of Claims 29, 31-34, 36-38, 40-42, 44-46, 48-49, 52, 54-71, 73, 75, 77-81, 83, 85-88, 90-93 and 96 under pre-AIPA 35 U.S.C. § 102(e) is in error.

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[1] "Another" is defined as other than applicant. *In re Land*, 368 F.2d 866, 151 U.S.P.Q. 621 (CCPA 1966); MPEP § 2136.04.

Election/Restrictions

In the Office Action, the Examiner withdrew Claim 95 from further consideration pursuant to 37 C.F.R. § 1.142(b). The Examiner states that Claim 95 is directed to an invention that is independent or distinct from the invention originally claimed because Claim 95 is clearly drawn to the subcombination. Applicant respectfully traverses this withdrawal and requests that Claim 95 be reinstated and examined in the instant application.

According to MPEP § 802.01, combination and subcombination inventions are dependent inventions. Therefore, it is improper to require a restriction between the two on the basis that they are independent. MPEP § 802.01. The Examiner's withdrawal of Claim 95 because it is a subcombination, independent of the invention as originally claimed, is thus in error.

Restriction between a combination and a subcombination is proper, however, if reasons for insisting on restriction are proved, i.e., separate classification, status, or field of search. MPEP § 806.05(c). Besides the Examiner having offered no such proof, Applicant respectfully submits that there are no good reasons for insisting on restriction.

Applicant strongly urges that the retraction mechanism of Claim 95 and the invention as originally claimed fall within the same art. The invention as originally claimed recites a syringe having a retraction mechanism, while the retraction mechanism of Claim 95 is for a syringe (see the preamble of Claim 95). The prior art for the retraction mechanism of Claim 95, therefore, is the same as the prior art for the invention as originally claimed. It, therefore, is not unduly extensive nor burdensome for this Examiner, during the prosecution of the instant application, to search the same prior art. In fact, it would be inefficient and unfair to the Patent Office and Applicant to require a single claim, Claim 95, to be examined in a separate application. Accordingly, any consideration of the patentability of Claim 95 would most efficiently be undertaken contemporaneously with the patentability of the pending claims by the same examiner.

In the "Amendment and Response to Restriction Requirement" dated April 10, 2002, Applicant provisionally elected Species 1 drawn to FIGS. 1-3 and submitted that

all claims were readable on FIGS. 1-3. Applicant herein reiterates that Claim 95 is readable on FIGS. 1-3.

Claim 95 recites a hollow housing having first and second open ends, as shown in FIGS. 1-3 at reference numeral 12. Claim 95 recites a spring and needle holder insertable into the housing through the second open end and grounded inside the housing, as shown in FIGS. 1-3 at reference numerals 24 and 22, respectively. A portion of the needle holder of Claim 95 extends forwardly through the first open end, as shown in FIGS. 1-3 at reference numeral 27. FIGS. 1-3 also show the needle holder providing an interior guide and the hollow housing providing an exterior guide for the spring during compression, as recited by Claim 95. Claim 95 recites the continuous retainer member disposed within the housing, the retainer member cooperating with the needle holder to maintain the spring in compression prior to retraction, as shown in FIGS. 1-3 at reference numeral 66.

Accordingly, it is respectfully requested that the requirement for restriction be withdrawn and Claim 95 be reinstated for consideration in the instant application.

Response to Objections to Drawings and 35 U.S.C. § 112 Rejections

To avoid being repetitive, Applicant addresses the objections to the drawings and the 35 U.S.C. § 112 rejections jointly.

Various objections to the drawings have been made. It is respectfully submitted that the corrected drawings accompanying this response and the arguments presented below overcome the Examiner's objections.

Claims 29-34, 36-42, 44-50, 52, 54-56 and 81-94 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. It is respectfully submitted that the arguments presented below and amendments to the specification, drawings and claims overcome these rejections.

The drawings have been corrected to clearly show reference numerals 64 and 66 pointing at different parts. The lead line of reference numeral 66 has been changed to clearly point to the continuous retaining member, while the lead line of reference numeral 64 points to the outwardly facing surface of head 30.

In further response to the office action, reference numeral (66) represents the continuous retaining member, as recited in Claims 29, 37, 45 and 54. The specification, as amended herein, clearly defines the continuous retaining member (66) "as a continuous, annular ring surrounding the circular inner head 72" of the needle holder (22). The retaining member (66) is continuous because it surrounds the inner head (72) of the needle holder (22). The retainer member (66) is not the same as the needle holder (22).

Reference numeral 76 represents the structure mounted in the front-end portion of the barrel, which is recited in Claims 30, 39 and 47. As described in the specification at page 15, lines 10-12, the front portion (26) of the needle holder (22) is "grounded or bottomed" inside front (76) of nose (16), so that no amount of pressure will allow needle holder (22) or needle (28) to move forward.

Claims 31, 34, 41 and 49 have been amended to delete the limitation "a part" and to recite a plunger carrying a tip which contacts the continuous retaining member. As shown in the drawings and the specification at, for example, page 17, lines 15-18, reference numeral 40 represents the tip of the plunger which protrudes to contact the upper surface of the retainer ring (66).

Reference numeral 49 has been added to FIG. 2 to clearly point out the means of force applied by the tip of the plunger, as recited in Claims 34 and 42. The specification has also been amended to clearly point out the means of force applied along arrow 49. The means of force applied by the tip of the plunger is the thumb force applied by the user, as supported at, for example, page 6, lines 9-15; page 15, lines 16-22; and page 16, lines 1-4.

Claims 38 and 46 have been amended to delete the limitation "the separable part" and to recite a variable chamber in the barrel behind the continuous retaining member, which has sufficient antecedent basis (see Claims 37 and 45). It is no longer necessary to point out what reference numeral represents the separable part, as the limitation was deleted from Claims 38 and 46.

Reference numeral 37 has been added to FIGS. 1-3 to clearly point out the rigid plunger seal element stop surface of Claim 54. The specification has also been

amended to clearly define the rigid plunger seal element stop surface (37) which acts as a plunger seal element stop.

Reference numeral 35 has been added to FIGS. 1 and 2 to clearly point out the supporting surface of Claim 56. The specification has also been amended to clearly define the supporting surface (35) having a plunger seal element fixed thereon.

Reference numeral 77 has been added to FIGS. 1 and 3 to clearly point out the annular shoulder of Claim 60. The specification has also been amended to clearly define the annular shoulder (77) that grounds the elongated needle holder inside the nose of the body.

As to Claim 81, the retainer member does in fact hold the spring in compression inside the nose prior to retraction. The specification at page 15, lines 1-6, discloses that the retainer member (66) is coupled to the inner head (72) of the needle holder (22) by a holding force which exceeds a retraction force applied to the underside of the inner head (72) by means of the end of the compressed spring (24). Both the retainer member and the needle holder prevent the spring from expanding. Therefore, the retainer member is clearly defined in Claim 81 because the retainer member does hold the spring in compression.

Claim 94 has been amended to delete the limitation "an element" and to recite "a tip" to better define the element that extends forwardly of the plunger seal to initiate retraction (see specification at, for example, page 17, lines 15-18).

Specification

Regarding the objection to the specification, an amendment to the specification accompanies this response. The amendment provides a proper antecedent basis for the continuous retaining member. Therefore, it is respectfully submitted that the amendment to the specification overcomes the Examiner's objection.

Response to 35 U.S.C. § 102 (b) Rejection

Claim 53 is rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,201,710 to Caselli ("Caselli"). To anticipate a claimed invention, a prior art reference must teach every aspect of the claimed invention. *Hybritech, Inc. v.*

Monoclonal Antibodies, Inc., 802 F.2d 1367 (Fed. Cir. 1986). In light of the amendments to Claim 53, it is respectfully submitted that Caselli does not teach every aspect of Applicant's invention as defined by amended Claim 53, and, therefore, does not anticipate Applicant's amended Claim 53.

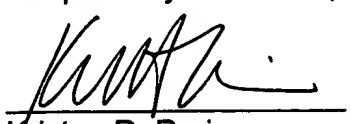
As amended, Claim 53 recites a syringe assembly having a retractable needle and a front end portion with an elongate biasing element and a one-piece needle holder. The needle holder has a back portion and a front portion. The back portion has a flat, blunt surface that forms at least part of a variable fluid chamber in a barrel and the front portion extends through the biasing element and protrudes forwardly beyond all other structural elements of the assembly except the needle.

FIGS. 1-5 of Caselli do not teach the flat, blunt surface of the back portion of the needle holder. Instead, Caselli teaches a sharp, circular edge (15) on the head (14) that breaks the diaphragm (35) to open opening (11) of cylinder (7) so that the needle can be withdrawn into cylinder (7) (column 2, lines 60-65; column 4, lines 53-56). The needle holder of Applicant's invention as defined by Claim 53 does not require a sharp edge to break a structure covering the opening of the barrel so that the needle may retract into the barrel.

Accordingly, Caselli does not anticipate Applicant's claimed invention as defined by Claim 53. Applicant requests that the rejection of Claim 53 under 35 U.S.C. § 102(b) be reconsidered and withdrawn.

Enclosed is a check for the payment of the fee for a one-month extension of time for filing this response for a small entity. It is believed that no additional fee is due for the submission of this paper. If this is incorrect, the Commissioner is hereby authorized to charge any additional fee that may be due in connection with this response to Deposit Account No. 12-1781 of Locke Liddell & Sapp LLP.

Respectfully submitted,



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Marked-Up Amendments To Specification and Claims

In the Specification

First full paragraph on page 15, lines 7-15 of the specification as originally filed:

> Importantly, retainer member 66 can be visualized as a continuous, [an] annular ring surrounding circular inner head 72. The location of retainer member 66 at the most constricted part of the transition zone where the nose begins and the relatively small area exposed to pressurized fluid in chamber 68 results in a high blowout pressure. Since the front portion 26 of the needle holder is grounded or bottomed inside front 76 of nose 16 at annular shoulder 77, no amount of pressure will allow needle holder 22 or needle 28 to move forward. Blowout pressure may be defined as the pressure in chamber 68 acting on the exposed area of retainer member 66 to produce a force sufficient to overcome the holding force such that retainer 66 could "blowout" by moving forward and prematurely release needle holder 22.

First full paragraph on page 13, lines 7-10 of the specification as originally filed:

> A plunger generally designated by the reference numeral 32 is disposed for use partially within barrel 14. The plunger has a head and seal generally referred to by reference numeral 34, in slidable sealed contact with the interior of barrel 14 of outer body 12. The plunger has a seal element 36 that is conventional and a retraction cavity 38 therein. Plunger seal element 36 fits in supporting surface 35 of the outer surface of head 34. Supporting surface 35 securely holds plunger seal element 36 in position and prevents plunger seal element 36 from longitudinal

movement. The inside wall of the transition zone 18 forms a rigid plunger seal element stop surface 37, which acts as a plunger seal element stop upon forward movement of plunger 32.

Last paragraph page 15, lines 16-22 and page 16, lines 1-4 of the specification as originally filed:

Some users have strong hands and might, at the outer limit in an emergency, be able to generate a force of as much as fifteen to eighteen pounds on the plunger during an injection. It is considered almost impossible for anyone to exert a force of more than eighteen pounds. This may be regarded as the maximum expected force which must be taken into account so that ring member 66 will not blowout while an injection is being made. The greatest cross sectional area of variable chamber 68 and the area of retainer member 66 exposed to fluid pressure are selected so that the blowout pressure is higher than the maximum pressure in chamber 68 expected to result from the maximum expected thumb force (as shown by arrow 49) applied to cap 48 during an injection. This ratio is preferably about two to one and more preferably about three to one or more so that the holding force holding the retraction mechanism in place can be kept at a comfortably low level while the blowout pressure remains high.

In the Claims

31. (Amended) The assembly of claim 29 wherein the plunger carries a tip [part] which protrudes to contact the continuous retaining member and release the retractable needle when retraction is initiated by pushing on the plunger.

34. (Amended) The assembly of claim 33 wherein the continuous retaining member is separated from the retractable needle by means of force applied by said tip [part] to said continuous retaining member when retraction is initiated by pushing on said plunger.

38. (Amended) The assembly of claim 37 wherein the continuous retaining member acts as a fixed seal for a variable chamber in the barrel behind the continuous retaining member [separable part].

41. (Amended) The assembly of claim 40 wherein the plunger carries a tip [part] which protrudes to contact the continuous retaining member and release the retractable needle when retraction is initiated by pushing on the plunger.

42. (Amended) The assembly of claim 41 wherein the continuous retaining member is separated from the retractable needle by means of force applied by said tip [part] to said continuous retaining member when retraction is initiated by pushing on said plunger.

46. (Amended) The assembly of claim 45 wherein the continuous retaining member acts as a fixed seal for a variable chamber in the barrel behind the continuous retaining member [separable part].

49. (Amended) The assembly of claim 48 wherein the plunger carries a tip [part] which protrudes to contact the continuous retaining member and release the retractable needle when retraction is initiated by pushing on the plunger.

50. (Amended) The assembly of claim 49 wherein the continuous retaining member is separated from the retractable needle by means of force applied by said tip [part] to said continuous retaining member when retraction is initiated by pushing on said plunger.

53. (Twice Amended) A syringe assembly having a retractable needle and a front end portion with an elongate biasing element and a one piece needle holder, the needle holder having a back portion and a front portion, the back portion having a flat, blunt surface that forms at least part of a variable fluid chamber in a barrel, the front portion extending through the biasing element[, a portion of the needle holder] and protruding forwardly beyond all other structural elements of the assembly except the needle.

94. (Amended) The syringe of claim 81 wherein the plunger comprises a tip [an element] that extends forwardly of the plunger seal to initiate retraction.